

AD_____

Award Number: DAMD17-01-1-0722

TITLE: Improving Quality of Life in Ovarian Cancer Patients: A Brief Intervention for Patients and their Partners

PRINCIPAL INVESTIGATOR: Sandra G. Zakowski, Ph.D.

CONTRACTING ORGANIZATION: Rosalind Franklin University of Medicine and Science
North Chicago, IL 60064

REPORT DATE: Sep 2006

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 30-09-2006		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 1 Sep 2005-31 Aug 2006	
4. TITLE AND SUBTITLE Improving Quality of Life in Ovarian Cancer Patients: A Brief Intervention for Patients and their Partners				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER DAMD17-01-1-0722	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Sandra G. Zakowski, Ph.D. E-Mail: Sandra.zakowski@rosalindfranklin.edu				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Rosalind Franklin University of Medicine and Science North Chicago, IL 60064				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT <p>The current study examines the effects of a psychological intervention that encourages emotional expression in ovarian cancer patients and their partners. Ovarian cancer patients (n=130) and their partners are randomly assigned to an intervention or a control group. Following Pennebaker's model, subjects in the intervention group are asked to write about their deepest thoughts and feelings regarding their cancer experience for 20 minutes each day for three consecutive days. The control group is asked to write about trivial non-emotional topics. Outcome variables including psychological distress, quality of life, and physical symptoms is assessed at baseline and over a period of nine months after the intervention (one week, three, six, and nine months).</p> <p>In accordance with our approved Statement of Work data collection is currently underway. To date 87 subjects have been enrolled and are at various stages of the data collection process. Data processing is continuing as planned, including data entry and verification, which has been completed for all subjects currently enrolled in the project. Preliminary data analyses are being conducted.</p>					
15. SUBJECT TERMS Quality of life, psychosocial intervention, stress					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	8	19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	5
Key Research Accomplishments.....	6
Reportable Outcomes.....	6
Conclusion.....	7

Introduction

The current study examines the effects of a psychological intervention that encourages emotional expression in ovarian cancer patients and their partners. Ovarian cancer patients (n=130) and their partners are recruited at Chicago area hospitals. Eligibility of patients includes ability to read and write in English, absence of any concurrent chronic condition or concurrent or prior history of psychiatric disorders, and having a spouse or partner. Patients are recruited between two months to five years after diagnosis, and after completion of active cancer treatment (e.g., surgery, radiation). They are also asked for permission to contact their spouse or partner for recruitment into the study. As it is our goal to recruit a partner for each patient to maximize effectiveness of the intervention, the only exclusion criteria for patients' partners will be inability to read and write in English or any psychiatric disorder that would preclude participation. Patients and their partners are randomly assigned to an intervention or a control group. Subjects in the intervention group are asked to write about their deepest thoughts and feelings regarding their cancer experience for 20 minutes each day for three consecutive days. The control group is asked to write about trivial non-emotional topics. Intervention Group: Subjects are told to write continuously for 20 minutes about their deepest thoughts and feelings about their cancer experience (spouses/partners will write about how they have been affected by the patient's illness), and about how it relates to other aspects of their lives, e.g., their family life, relationship with their spouse, sexuality, daily activities, work, social life, etc. The instructions are designed such that subjects will feel free to write about the aspects of their experience that are important to them. To encourage emotional expression, it is emphasized that their writing samples will be kept completely confidential and anonymous and will only be identified by the participant's number, not their name. The essays will later be processed by independent blind readers who have no knowledge of the participant's identity or group assignment. Finally, participants are told to not worry about style, grammar, or spelling and that no feedback will be provided to them regarding the contents of the essays. Control Group: Procedures follow standard protocols used in previous research. Subjects are asked to write for 20 minutes each day about a trivial non-emotional topic that is assigned to them (e.g., description of their routine daily activities). Subjects will be told to remain factual and not add any emotional content. All other procedures will be identical to the Intervention Group.

Outcome variables including psychological distress, quality of life, and physical symptoms are assessed at baseline and over a period of nine months after the intervention (one week, three, six, and nine months).

Specific Aim I: To examine the effectiveness of the emotional writing intervention for patients and their partners. **Specific Aim II:** To examine mechanisms for the effects of expressive writing. **Specific Aim III:** To begin to identify those individuals who will be most likely to benefit from this type of intervention.

Body

Task 1: Preparation for the study (month 1 to 2):

The research protocols have been developed including instructions for all aspects of the protocol and questionnaire packets for each assessment. Research assistants have been trained to administer all parts of the protocol including the intervention, all assessments, and debriefings.

Task 2: Data collection (month 2 to 36):

Collaborating physicians are referring research subjects on an ongoing basis. Currently a total of 87 participants have been recruited into the protocol and are at various stages of the data collection process. We encountered a number of unforeseen difficulties that have delayed patient recruitment over the course of the study period and which have prevented us from completing data collection as planned. First, there was a considerable delay of over five months by the DOD human subjects protection office as a result of which we were unable to begin recruitment until February of 2002. Second, the co-investigator on the grant who was responsible for patient recruitment, Dr. Peter Johnson, relocated to a medical center out of state, and despite efforts to recruit patients at that center for over a year, we were unable to collect data from that site. In the meantime we sought new collaborators at the original recruitment site, however, since Dr. Johnson's departure there had been no gynecological oncologists on staff until only recently. Over the past year we have established new collaborations with Drs. David Boruta and Janet Osborne at that site who have begun to recruit patients for the study. We have received referrals from our collaborators but recruitment has been slower than expected. The research assistants are conducting interviews and interventions and follow-up assessments are done at one week, 3, 6, and 9 months post-intervention as planned. We are keeping track of recruitment and subject follow-up using a computerized database (ongoing). Weekly research meetings are in place to deal with the day to day running of the project.

Task 3: Data processing (month 6 to 36):

Data spreadsheets have been set up and all data currently collected have been entered. Data verification is conducted periodically to ensure accuracy of data processing.

Task 4: Data analyses (month 34-36):

Preliminary data analyses have been conducted on the current sample (see results below). In addition, several manuscripts have been published combining this dataset with our comparable study of prostate cancer patients (see previous annual reports)

Key Research Accomplishments

- Research protocol and referral mechanisms are in place and continue to run as planned.
- A total of 87 subjects are enrolled in the study.
- Additional referrals are being obtained on an ongoing basis and patients are being screened for eligibility.
- Data entry and verification is conducted on an ongoing basis.
- Findings using this sample in combination with other data sets have been presented and published.
- Weekly research meetings are conducted.

Reportable Outcomes

The following aims are addressed below:

Specific Aim I: To examine the effectiveness of the emotional writing intervention for patients and their partners. **Specific Aim II:** To examine mechanisms for the effects of expressive writing. **Specific Aim III:** To begin to identify those individuals who will be most likely to benefit from this type of intervention.

Patients' were between 24 and 84 years old ($M=57.92$, $SD=12.85$), 97.70% were Caucasian, 70.5% currently married, 48.3% currently employed, and 33.3% had at least a college education.

First we examined whether there were any significant differences in demographic variables between conditions using ANOVA or chi-square analyses as appropriate. No significant differences emerged between conditions on any of the demographic variables (all $p's > .05$). There were also no significant baseline distress or personality differences across conditions. Therefore, none of the background variables were included as covariates in the analyses.

Manipulation Check

A manipulation check was included in order to verify the effectiveness of and subjects' compliance with the writing instructions. At the end of each writing session subjects rated how personal the essay was and to what extent they revealed their emotions in the essay. Total scores were examined collapsing across the three writing sessions revealing a significant condition effect on both sets of ratings, $F(1,84)=23.48$, $p<.001$, and $F(1,84)=33.42$, $p<.001$ respectively suggesting that the manipulation was effective.

Specific Aim I: To examine the effectiveness of the emotional writing intervention for patients and their partners.

On the current sample, there are no significant main effects for writing condition at follow-up.

Specific Aim II: To examine mechanisms for the effects of expressive writing.

Due to the lack of a condition main effect on this sample, mediators cannot be identified on the main effects, however we did examine mediators of the interaction effect (see below).

Specific Aim III: To begin to identify those individuals who will be most likely to benefit from this type of intervention.

Multiple regression analyses revealed individual differences regarding the benefits of the writing intervention:

Moderating role of Neuroticism

Multiple regression analysis entering Baseline Distress, Neuroticism, Condition, and the Condition by Neuroticism (N) crossproduct showed a significant main effect of baseline distress, $F(1,86)=90.88$, $p<.001$ and a significant Condition x Neuroticism interaction $F(1,83)=15.41$, $p<.001$ on distress at follow-up. As reported previously, there was no significant main effect of writing condition (Zakowski, et al., 2004). Regression lines plotted in accordance with recommendations by Aiken and West (1991) revealed that participants low on N exhibited reduced distress six months after writing about their cancer while participants high on N exhibited high levels of distress. Participants in the control condition reported distress levels that were in between irrespective of level of N (see Figure 1). This was confirmed when examining simple slopes (Aiken & West, 1991) which revealed a significant regression of distress on neuroticism in the experimental condition, $t=3.10$, $p=.004$, but no significant effect in the controls.

Next we examined whether hi N individuals would use more avoidant coping after emotional disclosure by conducting similar multiple regression analysis. Again there was a significant relationship between baseline avoidance and avoidance post-writing, $F(1,86)=34.81$, $p<.001$ and a significant N x Condition interaction, $F(4,87)=11.42$, $p=.001$. Regression plot revealed that results were in the expected direction, with participants high on N reporting the highest levels of avoidance of cancer-related reminders. Simple slope analysis revealed a significant positive relation between N and avoidance in the experimental condition, $t=3.36$, $p=.002$ and a non-significant effect in Controls.

Testing the hypothesis that hi N individuals would report more negative mood after emotional disclosure we conducted a multiple regression analysis with change in negative mood from pre- to post-writing across the three writing days as the dependent variable. In addition to a significant Condition main effect, $F(2,84)=5.11$, $p<.03$ there was a significant N x Condition interaction, $F(3,84)=5.02$, $p<.03$. Regression plot revealed that hi N participants exhibited the greatest increases in negative mood after writing about their cancer experience. Simple slope analysis revealed non-significant relationships between Neuroticism and negative mood change ($p's>.1$).

Neither avoidance nor negative mood change significantly affected the neuroticism by condition interaction on distress which remained significant after controlling for avoidance and mood change respectively, $F(1,87)=11.12$, $p=.001$; $F(1,84)=17.47$, $p<.001$ suggesting that neither of the variables could explain the interaction effect.

Moderating Role of Extraversion

Similar analyses were conducted using Extraversion as a moderating variable. In addition to the significant association between baseline and Time 2 GSI, there was also a significant main effect of Extraversion on GSI, $F(1, 85)=4.84$, $p<.05$ with high extraversion being associated with low GSI at follow-up. The extraversion by condition interaction was also significant, $F(1,83)=6.43$, $p=.01$ such that participants high in E were less distressed six months after emotional disclosure than those who had low E. Simple

slope analysis revealed a significant negative relation between extraversion and distress, $t=-2.86$, $p<.01$ in the experimental condition with no significant effect in the control condition.

Next we examined whether extraverts would be more likely to report positive affect in response to the emotional disclosure task. While there was a significant effect of experimental condition on positive mood change across the three writing days, $F(1,82)=6.50$, $p<.02$, neither extraversion nor the extraversion x condition interaction significantly predicted positive mood change ($p's>.1$).

Finally we examined the effect on avoidance one week after writing, predicting that extraverts would show either no increase in avoidance after emotional disclosure or a decrease. There was a significant main effect of baseline avoidance on avoidance one-week post-writing, $F(1,87)=34.81$, $p<.001$ and a significant main effect of extraversion on avoidance, $F(1,84)=4.84$, $p<.05$, suggesting high extraversion to be associated with low avoidance. However, the extraversion by condition interaction was not significant, $p>.1$.

Conclusions

The expressive writing intervention was not equally effective in all participants recruited to date. Individual differences in benefits were found, such that individuals low on trait Neuroticism were most likely to benefit from the intervention. No mechanisms for the effect have yet been identified. We will continue to recruit participants into the study as our new collaborations are developed and will continue to conduct analyses to address the study aims as more data are collected. The results presented above will be submitted for publication as soon as we have a sufficient number of participants. No changes to the current protocol or data analytic strategy are necessary at this time as we expect to enroll the target number of participants by study end.

Personnel: Sandra Zakowski, Virginia Boquiren, Sara Dittoe, Michele Herzer, Brian Schmaus, Angela Fidler and Noelle Pontarelli have received pay from the research effort.